

# **Strategic Review Outcome and Program Updates**

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company, announced on 29 May 2019 the results of the independent strategic review conducted with the assistance of Greenhill & Co., Inc.

- Formal strategic review period is complete.
- Company continues to evaluate out-licensing opportunities and potential merger candidates, but no assurance can be given that these efforts will lead to a proposal the Board can recommend to shareholders.
- Patient enrolment in BNC210 exploratory clinical trial to treat Agitation in elderly patients in a hospital/nursing home setting is now complete and top line data are expected by the end of June 2019.
- Company is building on learnings from the Phase 2 RESTORE trial and exposure-response analysis. A request has been submitted for a Type C meeting with the FDA to provide guidance on the design of a potential second Phase 2b trial of BNC210 in Post-Traumatic Stress Disorder (PTSD) using a solid dose formulation and potential eligibility for a Fast Track designation. The company expects feedback by CY3Q2019.
- The next inflection point for our collaboration with Merck & Co., Inc., Kenilworth NJ USA is no longer anticipated in 1H2019 and we are unable to provide further information at this time. We note that Merck & Co., Inc., Kenilworth NJ USA continues to conduct clinical development to evaluate the asset. We plan to update the market as and when more information is available.
- Costs have been further reduced and a capital and debt structure review is being conducted by management to determine the feasibility of funding future clinical trials. Any decision on this is unlikely to be made until the company has full feedback from its Type C meeting with the FDA.

Dr. Errol De Souza, Executive Chairman of Bionomics said, "Extensive discussions with potential counterparties in relation to monetising all or part of the Bionomics portfolio of clinical and pre-clinical assets did not identify a compelling alternative to continuing development and partnering discussions of those assets by Bionomics. We will continue to entertain credible proposals in relation to transactions that could add value to shareholders from any source. In the meantime, we continue to focus on advancing the pipeline while cutting operating costs to extend our cash runway. We anticipate reporting the top line data of our exploratory BNC210 clinical trial for the treatment of Agitation in elderly patients by the end of June 2019 and will define the strategy for BNC210 for the treatment of PTSD and other anxiety-related disorders following receipt of guidance from the FDA towards the end of CY3Q2019."

## FOR FURTHER INFORMATION PLEASE CONTACT:

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#### **About Bionomics Limited**

Bionomics (ASX: BNO) is a global, clinical stage biopharmaceutical company leveraging its proprietary platform technologies to discover and develop a deep pipeline of best in class, novel drug candidates. Bionomics' lead drug candidate BNC210, currently in Phase 2 for the treatment of agitation, is a novel, proprietary negative allosteric modulator of the alpha-7 ( $\alpha$ 7) nicotinic acetylcholine receptor. Beyond BNC210, Bionomics has a strategic partnership with Merck & Co., Inc., Kenilworth NJ USA (known as MSD outside the United States and Canada) and a pipeline of pre-clinical ion channel programs targeting pain, depression, cognition and epilepsy.

#### www.bionomics.com.au

### **Factors Affecting Future Performance**

This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this announcement that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' drug candidates (including BNC210), its licensing agreements with Merck & Co., Inc., Kenilworth NJ USA and any milestone or royalty payments thereunder, drug discovery programs, ongoing and future clinical trials, and timing of the receipt of clinical data for our drug candidates are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements.

There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward-looking statements, including unexpected safety or efficacy data, unexpected side effects observed in clinical trials, risks related to our available funds or existing funding arrangements, our failure to introduce new drug candidates or platform technologies or obtain regulatory approvals in a timely manner or at all, regulatory changes, inability to protect our intellectual property, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantage, as well as other factors. Results of studies performed on our drug candidates and competitors' drugs and drug candidates may vary from those reported when tested in different settings.